OCT 1 0 2006

K061660

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Kalamazoo, MI 49001
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stryker

Interventional Pain

510(k) Summary

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Device Sponsor: Stryker Interventional Pain
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

Registration No.: 3005182723

Trade Name: Stryker RF Parallel BiPolar Adaptor Cable

Common Name: Electrosurgical Connecting Cable

Classification Name: Probe, Radiofrequency Lesion (GXI)

Equivalent to:
K043442 Stryker RF Coaxial Bipolar Electrodes and Cannulae
K020354 Baylis Pain Management Generator
K053082 Baylis Pain Management Cooled Probe
K031951 Baylis Transdiscal System
K052878 NeuroTherm NT 1000 RF Lesioning System

Device Description: The Stryker RF Parallel BiPolar Adaptor Cable will be used in conjunction with the Stryker RF Generator, Electrodes and Cannulae to create radiofrequency lesions in nerve tissue. The generator applies temperature-controlled, radiofrequency (RF) energy into targeted nerve tissue via a pair of electrode probes.

Indications for Use: The Stryker RF Parallel Bipolar Adaptor Cable is intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications in combination with the separately cleared Stryker RF Generator, Electrodes and Cannulae.
Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia, and Rhizotomy

Substantial Equivalence (SE) Rational: The Stryker RF Parallel BiPolar Adaptor Cable has the same intended use as all of the predicate devices. This device and the predicate devices have the same technological characteristics, the same operating principles and have similar performance characteristics.

Safety and Effectiveness: Based upon the comparison to the predicate devices, the Stryker RF Parallel BiPolar Adaptor Cable is substantially equivalent to a legally marketed device.

K061660

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Submitted by: Jean Sheppard
Regulatory Analyst

Signature

Date submitted: September 26, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

Stryker Instruments
% Ms. Jean Sheppard
Regulatory Analyst
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K061660
Trade/Device Name: Stryker RF Parallel BiPolar Adaptor Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, GXI
Dated: September 26, 2006
Received: September 27, 2006

Dear Ms. Sheppard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Per

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K061660

Device Name: Stryker RF Parallel BiPolar Adaptor Cable

Indications for Use

The Stryker RF Parallel Bipolar Adaptor Cable is intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications in combination with the separately cleared Stryker RF Generator, Electrodes and Cannulae.

Examples of procedures include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, and Rhizotomy

Prescription Use __X__ and/or Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K061660